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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,614	10/08/2003	Mark G. Currie	0701.213A	7281
2264	7590	05/15/2006	EXAMINER	
HESLIN ROTHENBERG FARLEY & MESITI P.C.			BADIO, BARBARA P	
5 COLUMBIA CIRCLE			ART UNIT	
ALBANY, NY 12203			PAPER NUMBER	

1617

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/681,614

Applicant(s)

CURRIE ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/2004, 6/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

**First Office Action on the Merits**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they lack a period and, thus, the metes and bound of the claimed invention is unclear.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 6, 11, 12, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Axelsson et al. (US 4,693,999).

Axelsson et al. teaches anti-inflammatory and antiallergic compositions containing steroid esters such as dexamethasone-21-palmitate, budesonide-21-palmitate, beclomethasone-21-palmitate-17-propionate and betamethasone-21-

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palmitate (see the entire article, especially col. 2, line 1 – col. 3, line 40; examples 1-27; claims 1-7). The reference also teaches (a) dexamethasone-21-palmitate is known to be useful in the treatment of arthritis and (b) formulation for inhalation (see especially col. 1, lines 34-36; col. 5, lines 27-31; col. 10, Example 2). The compounds, compositions and method of use taught by the reference are encompassed by the instant claims.

5. Claims 1, 2, 11, 12, 15 and 17-19 are rejected under 35 USC 102(b) as being anticipated by Axelsson et al. (US 5,888,995).

Axelsson et al. teaches steroid esters of glucocorticosteroids such as budesonide 21-palmitate having anti-inflammatory and antiallergic activities (see the entire article, especially col. 1, line 45 – col. 2, line – col. 4, line 22; examples 1-4, 6, 7, etc.). The reference teaches various routes of administration including inhalation (see col. 6, lines 22-65) and the utilization of glucocorticosteroids in the treatment of asthma and rhinitis (see col. 1, lines 8-22, 51-57; col. 1, line 66 – col. 2, line 14). The compounds, compositions and use taught by the reference are encompassed by the instant claims.

6. Claims 1, 2, 4, 5, 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Akaboshi et al. (JP 07277987).

Akaboshi et al. teaches several cyclic acetal anti-inflammatory steroids such as budesonide 21-palmitate, triamcinoloneacetonide 21-palmitate and fluorcinoloneacetonide 21-palmitate (see the attached English Abstract). The

compounds, compositions and use taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2 and 4-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelsson et al. (US 4,693,999).

Axelsson et al. teaches anti-inflammatory and antiallergic compositions containing steroid esters such as dexamethasone-21-palmitate, budesonide-21-palmitate, beclomethasone-21-palmitate-17-propionate and betamethasone-21-palmitate (see the entire article, especially col. 2, line 1 – col. 3, line 40; examples 1-27; claims 1-7). The reference also teaches (a) dexamethasone-21-palmitate is known to be useful in the treatment of arthritis and (b) formulation for inhalation (see especially col. 1, lines 34-36; col. 5, lines 27-31; col. 10, Example 2).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, it would have been obvious to the skilled artisan in the art at the time of the present invention to utilize any of the species of the genus taught by the reference, including those of the instant claims, with the reasonable

expectation that the compound(s) would be useful as anti-inflammatory and antiallergic agents as taught by Axelsson et al.

Claims 13, 14 and 16-17 further differ from the reference by reciting inflammatory and allergic diseases not exemplified by the reference. However, the conditions recited by the instant claims are well-known inflammatory/allergic conditions (see for example, US 7,012,091, col. 1, lines 16-18; US 5,283,268, col. 19-43). Therefore, the utilization of anti-inflammatory/antiallergic agents as taught by Axelsson et al. in the treatment of the inflammatory/allergic conditions as recited by the instant claims would have been obvious to the skilled artisan in the art at the time of the present invention.

9. Claims 1, 2, 4, 5 and 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable Axelsson et al. (US 5,888,995).

Axelsson et al. teaches steroid esters of glucocorticosteroids such as budesonide 21-palmitate having anti-inflammatory and antiallergic activities (see the entire article, especially col. 1, line 45 – col. 2, line – col. 4, line 22; examples 1-4, 6, 7, etc.). The reference teaches various routes of administration including inhalation (see col. 6, lines 22-65) and the utilization of glucocorticosteroids in the treatment of asthma and rhinitis (see col. 1, lines 8-22, 51-57; col. 1, line 66 – col. 2, line 14).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, it would have been obvious to the skilled artisan in the art at the time of the present invention to utilize any of the species of the genus taught by the reference, including those of the instant claims, with the reasonable

expectation that the compound(s) would be useful as anti-inflammatory and antiallergic agents as taught by Axelsson et al.

Claims 13, 14 and 16 further differ from the reference by reciting inflammatory and allergic diseases not exemplified by the reference. However, the conditions recited by the instant claims are well-known inflammatory/allergic conditions (see for example, US 7,012,091, col. 1, lines 16-18; US 5,283,268, col. 19-43). Therefore, the utilization of anti-inflammatory/antiallergic agents as taught by Axelsson et al. in the treatment of the inflammatory/allergic conditions as recited by the instant claims would have been obvious to the skilled artisan in the art at the time of the present invention.

10. Claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Axelsson et al. (US 5,888,995) in view of Diassi et al. (US 3,079,384) in combination.

Axelsson et al. teaches steroid esters of glucocorticosteroids such as budesonide 21-palmitate having anti-inflammatory and antiallergic activities (see the entire article, especially col. 1, line 45 – col. 2, line – col. 4, line 22; examples 1-4, 6, 7, etc.). The reference teaches various routes of administration including inhalation (see col. 6, lines 22-65) and the utilization of glucocorticosteroids in the treatment of asthma and rhinitis (see col. 1, lines 8-22, 51-57; col. 1, line 66 – col. 2, line 14).

The instant claim differs from the reference by reciting a compound wherein the ketal moiety is substituted with a cyclohexyl group. However, Diassi et al. teaches similar steroid esters having anti-inflammatory activity and an equivalent between substituents on the ketal such as hydrogen, lower alkyl and monocycloalkyl groups (see

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the entire article, especially col. 1, lines 29-72; col. 6, lines 14-23). Therefore, it would have been obvious to the skilled artisan in the art at the time of the present invention to modify the compounds taught by Axelsson, including budesonide 21-palmitate by replacing the propyl group on the ketal with a cycloalkyl group such as cyclohexyl, with the reasonable expectation that the compounds formed would have anti-inflammatory property as taught by Axelsson and Diassi.

### ***Telephone Inquiry***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badlo, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
May 11, 2006